REMARKS

Applicant and Applicant's representative thank the examiner and the examiner's supervisor for taking the time to discuss issues relating to patentability of the above-identified application during the examiner interview held April 2, 2008. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1-3, 6-10, 14-15 and 28-33 are pending, wherein claims 1, 2, 8-10, 14, 28-29 and 32 have been amended and claim 4 was cancelled. Claims 11-13 are currently withdrawn from consideration. Nevertheless, Applicant requests rejoinder of claims 11-13 upon the allowance of claim 1 from which they depend, as they recite a method of making the device of claim 1.

I. INTRODUCTION

As discussed during the examiner interview, the present invention relates to bone implant devices that are specifically formulated and constructed as to reliably encase a bone growth material (*e.g.*, a dry granular material) within a dry and initially non-adhesive covering, wherein the covering becomes sticky and gelatinous upon contact with water so as to render it adhesive to bone tissue. The implant device does not lie passively next to bone tissue but rather actively adheres itself to the bone tissue. This is an important and inventive advancement over the art of record. None disclose, either literally or inherently, an implant device that includes a dry covering that is initially dry and which completely encapsulates and retains a bone growth material and which becomes sticky and gelatinous upon contact with water so as to render it adhesive to bone tissue.

In *KSR v. Teleflex*, the Supreme Court rightfully concluded that it would have been obvious to the skilled artisan to substitute a mechanical position sensor with a well-known electronic substitute that was known and used in similar technologies. Substituting mechanical devices with corresponding electronic devices that provide the same function was seen by the Supreme Court as part of a larger, and clearly obvious, technological and market trend. The Supreme Court did not, however, hold that an invention is obvious merely because all the claimed elements can be found in the prior art. The Supreme Court stated the exact opposite: "As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 127 S. Ct. at 1741. "A fact finder [*e.g.*, examiner] should be aware, of course,

of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*, 383 U.S., at 36 (warning against a 'temptation to read into the prior art the teachings of the invention in issue' and instructing courts to 'guard against slipping into the use of hindsight.'" *KSR*, 127 S. Ct. at 1742.

II. ART REJECTION

The Office Action rejects claims 1-4, 6-10, 14-15 and 28-33 under 35 U.S.C. § 103(a) as being unpatentable over Tormala et al. (U.S. 4,863,472) taken with Silverberg (U.S. 4,755,184), Levy (U.S. 5,292,253) and Vyakarnam et al. (U.S. 6,306,424), and further in view of Kenyon et al. (U.S. 2,423,707). In response, Applicant submits that the applied art, when considered *as a whole*, neither teaches nor suggests the combination of limitations recited in the claims.

A. Tormala et al. is not an Appropriate Reference for Rejecting the Claims Because it Explicitly Teaches Away from a Bone Implant Device Having a Covering That Completely Encapsulates the Bone Growth Promoting Material

According to the Supreme Court and the newly promulgated examination guidelines issued by the USPTO, an invention is not obvious over a reference that teaches away from the specific combination of elements of the claimed invention:

> *United States v. Adams*, 363 U.S. 39, 51-52, 148 USPQ 479, 483 (1966). In *Adams*, the claimed invention was to a battery with one magnesium electrode and one cuprous chloride electrode that could be stored dry and activated by the addition of plain water or salt water. Although magnesium and cuprous chloride were individually known battery components, the Court concluded that the claimed battery was nonobvious. The Court stated that '[d]espite the fact that each of the elements of the Adams battery was well known in the prior art, to combine them as did Adams required that a person reasonably skilled in the prior art must ignore' the teaching away of the prior art that such batteries were impractical and that water-activated batteries were successful only when combined with electrolytes detrimental to the use of magnesium electrodes. *Id.* at 42-43, 50-52, 148 S. Ct. at 480, 483.

USPTO Examination Guidelines, Fed. Reg., Vol. 72, No. 195 (Oct. 10, 2007), 57529, n. 48.

As in *Adams*, Tormala et al. disparages, and therefore expressly teaches away from, a structure similar to the claimed invention (*i.e.*, a bone implant having a covering that completely encapsulates a bone growth promoting material). Tormala et al. also teaches that it is critical to

provide a large opening on the underside of the device that is larger than the size of bone graft particles:

> The movements of the bone graft powder can be prevented also by closing the particles into a porous, flexible casing, whose pores are smaller than the particle size of the powder, but which pores are big enough to allow the growth of tissues through the pores. Such casing has been described in EP-patent application No. 82621. Porous, flexible casings, which have been manufactured e.g. of collagen or of resorbable (in tissue degradable) polymer, into which casings the bone graft powder is closed, separate, however, the bone graft particles and bone tissue surface from each other. *When the direct contact of bone graft powder particles to the surface of the bone tissue is prevented, the growth of the bone tissue into the casing becomes more difficult and it may be even totally prevented.* In such a case only connective tissue grows into the casing like Gongloff et al. found in animal experiments (R. K. Gongloff and C. K. Montgomery, J. Oral. Maxillofac. Surg., 43 (1985) 645; R. K. Gongloff, W. Whitlow and C. K. Montgomery, J. Oral. Maxillofac. Surg., 43 (1985) 570).
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> In this invention we have found unexpectedly that the movements of bone graft powder can be effectively prevented and on the other hand, the rapid growth of bone tissue into the bone graft powder can be obtained by putting on the bone surface during operation a supporting structure which is manufactured at least partially of resorbable polymer, copolymer or polymer blend and which is of its form chute-like, box-like, a flat tube or a bag. The bone graft powder is located inside and/or below this supporting structure and this supporting structure includes such open porosity, which allows the surrounding tissues to grow through the supporting structure but which prevents the migration of the bone graft powder through the pores outside the supporting structure. *Especially that part of the supporting structure, which is located against bone surface* ***contains at least one orifice, whose size is bigger than the size of pores of the supporting structure and bigger than the size of the bone graft powder particles.*** *This orifice makes possible growth of the bone tissue into the inside of the supporting structure. Because* ***the orifice of the supporting structure is bigger than the particles of the bone graft powder*** these get through the orifice into direct contact with the bone and therefore the bone tissue can rapidly grow inside of the supporting structure into the bone graft powder. FIG. 1 shows schematically a typical, chute-like supporting structure of the invention, ***in whose bottom is an orifice to help the ingrowth of bone tissue*** (the orifice has been drawn by a dot-line).

Col. 2, lines 10-59 (emphasis added).

Independent claims 1 and 28 as amended each requires that "the dry and initially non-adhesive covering forms a continuous outer cover of the implant device so as to completely encapsulate and retain the bone growth promoting material within the enclosed space." This limitation excludes implant structures that have a cover with "at least one orifice, whose size is bigger than ... the size of the bone graft powder particles" (*e.g.*, as taught at col. 2, lines 46-48 and depicted in Figures 2b and 2e of Tormala et al.). Otherwise, the covering would not be able

to form "a continuous outer cover of the implant device so as to completely encapsulate and retain the bone growth promoting material within the enclosed space". Thus, not only do claims 1 and 28 define a structure that excludes the critical enlarged orifice of Tormala et al., they also define a covering that completely encapsulates the bone growth promoting material.[1]

Because Tormala et al. expressly teaches away from a device that only includes pores that are smaller than the bone graft powder retained within the implant (*i.e.*, a covering that completely encapsulates the bone graft powder), both the Supreme Court decision in *Adams* and the new USPTO examination guidelines lead to the conclusion that the claims of the present application are nonobvious over Tormala et al. Accordingly, Applicant submits that Tormala et al. is not a proper reference for rejecting the claims of the present application and should be ignored as constituting a clear teaching away when considering the patentability of the claims of the present application.

B. Tormala et al. and Silverberg are not Properly Combinable Because Tormala et al. Disparages the Implant Device of Silverberg

As discussed above, Tormala et al. disparages and therefore expressly teaches away from a device having a continuous porous outer covering that completely encapsulates bone graft granules. Tormala et al., col. 2, lines 16-24 (disparaging a continuous porous casing that completely encapsulates bone granules as preventing "direct contact of the bone graft powder particles to the surface of the bone tissue" which makes "growth of the bone tissue into the casing ... more difficult and it may be even totally prevented"). Silverberg discloses an implant in which the porous outer covering is continuous and completely encases the bone prosthetic particles. *See, e.g.*, Figure 1; col. 5, line 4 (the implant casings were was formed as "tubes"). Because Tormala et al. explicitly disparages the implant device of Silverberg, one of skill in the art would not have logically combined Tormala et al. and Silverberg in rejecting the claims of

[1] Although Tormala et al. discloses an optional covering over the enlarged orifice, such a covering is described as either "a thin ceramic plate with open porosity" or a film such as "Poloxamer-polymeric film". Col. 3, lines 10-14. Claims 1 and 28 require that the covering that completely encapsulates the bone growth promoting material to consists essentially of gelatinizable gauze, oxidized cellulose, oxidized regenerated cellulose, and/or gelatinizable cat gut. Although Tormala et al. allegedly discloses one or more of these materials (col. 4, lines 21-24), it is noteworthy that none are used to cover the enlarged orifice. This further emphasizes the clear differences between the claimed invention and Tormala et al.

the present application. As a result, the combination of Tormala et al. and Silverberg in rejecting an implant device having a continuous outer covering that completely encapsulates a bone growth promoting material is improper.

C. The Remaining References Fail to Teach or Suggest the Combination of Limitations Recited in the Claims as Amended

The claims are patentable over the remaining references (*i.e.*, Silverberg, Levy, Vyakarnam et al. and Kenyon et al.) because they do not teach or suggest a bone implant having the combination of features recited in the claims as amended. Silverberg discloses a bone augmentation implant that is made from polyglycolide or other material that does not become gelatinous or sticky upon being contacted with water. In the previous amendment, Applicants provided evidence that polyglycolide is a non-water soluble and non-gelatinizable material commonly used in forming resorbable implantable devices. The term "resorbable" simply means that, over time, enzymes in the body are able to hydrolyze and resorb the glycolide monomers. *See* Tormala et al., col. 3, lines 28-31. Thus, although Silverberg. disclose covers made of "resorbable" materials, it does not teach or suggest a cover that is formulated so as to become sticky and gelatinous upon contact with water, either explicitly or inherently.

The mechanism by which the casing of Silverberg is absorbed further emphasizes that it lacks the property of becoming sticky and gelatinous upon contact with water. "Progressive absorption of the mesh along with the simultaneous ingrowth of connective tissue" (col. 3, lines 52-53) clearly emphasizes that the casing material of Silverberg only breaks down slowly over time (*i.e.*, in the same time frame as tissue growth, which is known to take weeks or months) (*e.g.*, col. 6, line 47 – col. 9, line 47). According to Silverberg, "the mesh was visible at 2 and 6 weeks" (col. 9, line 37) further emphasizing the slow breakdown of the casing.

Moreover, it would be contrary to Silverberg to substitute the casing materials disclosed therein with materials such as those recited in claims 1 and 28, which become sticky and gelatinous upon contact with water. The method by which the implant device of Silverberg is implanted involves using a syringe. Col. 4, lines 9-13; Figure 2. "The implant is typically ***wetted*** with sterile saline solution prior to installation ***to facilitate lubrication***" (col. 4, lines 13-15) (emphasis added). Thus, the casing material employed in Silverberg becomes better lubricated when contacted with a saline solution (*i.e.*, water). If one were to substitute the casing material disclosed in Silverberg with a covering material that becomes sticky and gelatinous

upon contact with water, it would prevent or inhibit lubrication with water. Instead, wetting the implant device with saline solution would yield an implant device having a sticky and adhesive covering, the very opposite of "facilitate[ing] lubrication" as taught in Silverberg.

In short, substituting the water lubricatable casing material of Silverberg with a material that becomes sticky and gelatinous with water would render the Silverberg device unsuitable for its intended purpose. For this reason, Silverberg implicitly teaches away from an implant device having a dry and initially non-adhesive covering comprised of a water absorbing gelatinizable material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water so as to render it adhesive to bone tissue. Because Silverberg implicitly teaches away from the claimed implant device, one of skill in the art would not have substituted the water-lubricatable casing of Silverberg with any of the covering materials recited in claims 1 and 28 as amended (*i.e.*, gelatinizable gauze, oxidized cellulose, oxidized regenerated cellulose, and/or gelatinizable cat gut).

The remaining references do not teach or suggest a bone implant having a covering that is initially non-adhesive and which is designed to encapsulate a bone grown material and become sticky and gelatinized upon exposure to water. Levy discloses a moldable putty comprised of calcium-containing material and a protein gel. Abstract. The protein gel as disclosed in Levy does not, nor can it, function as a "covering" to encapsulate and retain bone growth material within the initially dry covering, which becomes sticky and gelatinous upon contact with water. Thus, Levy does not provide any motivation to obtain the claimed implant of the present invention. The skilled artisan would not have known how or why to manufacture the claimed bone implant in view of the combined teachings of Silverberg, Tormala et al. and Levy. Moreover, as discussed above, Tormala et al. explicitly teaches away from the claimed bone implant device of the present application, and Silverberg teaches a covering that becomes better lubricated when wetted with saline solution, not sticky and adhesive.

Vyakarnam et al. discloses a foam composite for the repair or regeneration of tissue, including bone. Col. 7, line 27 – col. 8, line 15. For bone repair, Vyakarnam et al. discloses a device that is made from one or more polylactide or polylactone polymers, such as polyglycolide, polylactic acid, and polycaprolactone. Such materials are hydrophobic and not water gelatinizable. They do not become sticky and gelatinous upon contact with water. Thus, Vyakarnam et al. does not provide any motivation to obtain the claimed implant of the present invention. The skilled artisan would not have known how or why to manufacture the claimed

bone implant in view of the combined teachings of Silverberg, Tormala et al., Levy and Vyakarnam et al.

Finally, Kenyon et al. discloses a fabric or gauze of uniformly oxidized cellulose. Such a material might be expected to become sticky and gelatinous upon contact with water. However, Tormala et al. explicitly teaches away from the claimed bone implant device of the present application, and Silverberg discloses a covering that is capable of become better lubricated when wetted with saline solution. Thus, one of skill in the art would not have known how or why to manufacture the claimed bone implant in view of the combined teachings of Silverberg, Tormala et al., Levy, Vyakarnam et al. and Kenyon et al.

III. ENABLEMENT

During the examiner interview, the examiners suggested that the present application might have provided specific examples of materials that are gelatinizable in water so as to become sticky and gelatinous upon contact with water rather than identifying such materials generically. Applicant agrees that, in hindsight, such examples might have been useful in more clearly illuminating the differences between the claimed invention and the implant devices of the prior art. Nevertheless, the use of the term "gelatinizable" provides a clear criterion to one of skill in the art when selecting a material from which to construct the initially dry and non-adhesive covering that encapsulates and retains the bone growth material.

By way of example, starch is a well-known and ubiquitous material used in industry and foodstuffs. "Starch" is a generic term that describes a wide variety of different materials having greatly varying properties. Native starch granules, from which all other forms of starch are derived, are insoluble in water and do not normally gelatinize in cold water. It is generally necessary to modify native starch through the input of energy in order to the starch to become gelatinized in water (*e.g.*, by heating to the gelatinization temperature in water or by grinding to physically break down the starch granule wall). Nevertheless, if one were to use the term "modified starch" or "pregelatinized starch", one of ordinary skill in the art would readily understand which type of starch to use and which not to use (*e.g.*, native starch would be excluded).

In the context of the present invention, use of the term "gelatinizable gauze" clearly differentiates between ordinary gauze made from cotton or other non-gelatinizable fibers and materials which are gelatinizable. One of ordinary skill in the art would know how to make the

selection of materials once the criterion of material selection is identified. In Silverberg, for example, an exemplary casing material selection criterion is that wetting the implant with saline solution should "facilitate lubrication". That means that one of skill in the art *would not* select materials such as "gelatinizable gauze, oxidized cellulose, oxidized regenerated cellulose, or gelatinizable cat gut" that become sticky and gelatinous upon contact with water. On the other hand, the present application discloses the desirability of selecting such materials instead of materials disclosed in Silverberg that do not become sticky and gelatinous upon contact with water.

At the time of filing the present application, there were several materials known to those of skill in the art which could be used to form a covering that becomes sticky and gelatinous upon contact with water. Examples include certain types of oxidized cellulose sold under the names Novocell and Oxycell. Indeed, such examples of oxidized cellulose are currently preferred materials from which to make implant coverings. Moreover, as pointed out in the Office Action, Surgicel is an example of a type of oxidized regenerated cellulose which may have the claimed property of becoming sticky and gelatinous upon contact with water. However, although Tormala et al. discloses the optional use of this or other materials "*[i]n addition to* the above polymers" listed in Table I (which clearly do not have the claimed properties), Tormala et al. expressly teaches away from manufacturing an implant device in which the covering "consists essentially of this material" ***and*** entirely encapsulates the bone growth promoting material. On the other hand, Silberberg implicitly teaches away from materials that become sticky and gelatinous upon contact with water as they would lack the ability to become better lubricated when wetting with saline solution. Accordingly, though the claimed materials were known, it would have been contrary to both Tormala et al. and Silverberg to construct an implant device using such materials in the claimed manner.

IV. CONCLUSION

In view of the foregoing, Applicant submits that the claims as amended are in allowable condition. In the event the Examiner finds any remaining impediment to a prompt allowance of

this application that may be clarified through a telephone interview or which may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 5th day of April 2008.

Respectfully submitted,

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